

REMARKS

Status of the Claims

Claims 1, 3-12, 14, 15, 17, 18, 20, 21, 23 and 24 are pending. No amendments have been made by way of the present submission, thus, no new matter has been added.

Rejections Under 35 U.S.C. §§ 102(b) and/or 103(a)

Claims 1, 3-12, 14, 15, 17, 18, 20, 21, 23 and 24 remain rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Hansen, WO 98/54961 (hereinafter referred to as "Hansen"). (*See*, Office Action of April 25, 2007, at page 2, hereinafter, "Office Action"). Applicants traverse the rejection as set forth herein.

The Examiner objects to Applicants' reference to literature published after the priority date of the present application, and after the publication date of Hansen in particular, to refute the disclosure of Hansen. (*Id.* at page 4). The Examiner also contends that even eppendorf tubes may be centrifuged at speeds that are encompassed by the range presently recited in claim 1. (*Id.* at page 5). Additionally, the Examiner comments on Applicants' referral to the centrifugation of plant protoplasts because protoplasts have "special structural and anatomical" features that require special handling, and lower G forces to prevent their destruction. (*Id.*). The Examiner states that reference to such lower speeds in the context of plant protoplasts is unrelated to the present claims. (*Id.*). The Examiner comments further upon Applicants' allegation of unexpected results, made in the last reply at page 8, second paragraph. (*Id.* at page 6). The Examiner states that the unexpected results observed by Applicants, as reported in the

specification, are not commensurate in scope with the subject matter encompassed by the claims.
(*Id.*).

In summary, the Examiner continues to allege that since an Eppendorf tube is used in Hansen, centrifugation must be conducted in Hansen. However, as is well-known in the art of biotechnology, Eppendorf tubes are often used simply as a vessel for holding a sample even when there is no intention of centrifuging the sample. Even if an Eppendorf tube is used, it does not always mean that centrifugation was performed. The Examiner's allegation is contrary to the real experimental procedures.

The Applicants have thus far insisted the following to be true: "Since type I callus is hard and dense, and since the immature embryo is sufficiently large and heavy, it immediately sinks in water. Therefore, there is no need to centrifuge the callus at all, and actually nobody conducts centrifugation for collecting the type I callus. Especially, to carry out the centrifugation at 1000G is unimaginable." To support this contention, Applicants cited to the standard text reference of "PLANT TISSUE CULTURE MANUAL Supplement 1."

In response to this citation, the Examiner states that these protocols were published in 2006, so that they do not show the state of the art at 1998 when Hansen was published. The Examiner further contends that especially in the field of biotechnology, technology has advanced greatly in 8 years. It is true that high technologies may change substantially in 8 years in the field of biotechnology. However, the issue here is not a high technology, but whether a person of ordinary skill in the art performs centrifugation or not in order to collect a sample such as type I callus or immature embryo.

In view of the fact that these samples (tissues) are sufficiently large and heavy, so that they immediately sink in water, a protocol wherein a centrifugation treatment is not conducted after placing the type 1 culture or immature embryo in water would not be changed between 1998 and 2006. That is, the fact that centrifugation treatment is not performed on the type 1 callus or immature embryos in the protocol of 2006 is clearly indicative of the fact that this step was also not carried out in 1998. This physical property of these types of tissues has not changed between the years 1998 and 2006.

Applicants submit herewith the Declaration of Yukoh HIEI under 37 C.F.R. § 1.132. As shown in the declaration, when the sample is accelerated at 760G, the GUS expression was almost the same as in the cases where the centrifugation treatment was not performed. In contrast, when the sample was accelerated at 1000G, GUS expression was about 3 to 4 times that in the cases where the centrifugation treatment was not performed. That is, when the centrifugal acceleration is 1000G or more, the transformation efficiency is largely increased. This effect is clearly an unexpectedly superior result.

Thus, the Examiner must weigh the presently submitted evidence of non-obviousness properly against any alleged finding of obviousness. *Graham v. John Deere*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966) has provided the controlling framework for an obviousness analysis. A proper analysis under 35 U.S.C. § 103(a) requires consideration of the four *Graham* factors of: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims that are at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating any evidence of secondary considerations (e.g., commercial

success; unexpected results). (*See, Graham v. John Deere*, 383 U.S. at 17, 148 U.S.P.Q. at 467).

The Examiner must therefore properly consider and weight the fourth factor of this analysis.

Furthermore, as stated in the M.P.E.P. at § 716.02, “[a] greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue.” (*See, M.P.E.P.*, at § 716.02, citing *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985)). The M.P.E.P. further states that, “[e]vidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (*i.e.*, demonstrating “synergism”).” (*See, Id.*, citing *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)). Applicants understand that they, “must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage.” (*See, Id.*, citing *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991)). Applicants believe they have shown, both through the presently submitted Declaration, and the disclosure of the specification, the requisite evidence of unexpected results.

Furthermore, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. (*See, In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992)). Applicants reiterate for further consideration their contention that any cited reference used for a rejection under 35 U.S.C. § 103(a) must be considered in its entirety, *i.e.*, as a whole, including those portions that would lead away from a claimed invention. (*See, W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied,

469 U.S. 851 (1984)). Therefore, the cited reference actually teaches away from the presently claimed invention because methods commonly used in the art did not use centrifugation at all. Even if one of ordinary skill in the art did use centrifugation, it would be at a low force of 100G. Applicants respectfully submit that it is not *prima facie* obvious to modify Hansen to include centrifugation at such a high force as presently claimed unless the reference suggests an advantage to be gained from the modification. (*See, In re Sernaker*, 217 USPQ 1, 6 (Fed. Cir. 1983)).

As to the allegation of anticipation, Applicants reiterate that Hansen does not disclose all of the limitations of the presently claimed invention, as previously argued in their reply of November 30, 2006. Since Hansen does not disclose each and every limitation of the presently claimed invention, at least as recited in amended claim 1, Hansen cannot anticipate the presently claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See, Verdegual Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Therefore, in light of the foregoing, reconsideration and withdrawal of the anticipation rejection and/or obviousness rejection of claims 1, 3-7, 12, 14, 15, 17, 18, 20, 21, 23 and 24 are respectfully requested.

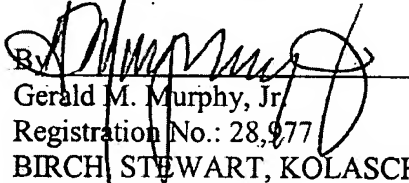
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: October 24, 2007

Respectfully submitted,


By _____

Gerald M. Murphy, Jr.

Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicants

Attachments: Declaration of Yukoh HIEI under 37 C.F.R. § 1.132, 5 pages